UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
[illegible]	[illegible]	[illegible]	[illegible]

EXAMINER	
[illegible]	

ART UNIT	PAPER NUMBER
1633	9

[illegible]
MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO CA 92130-2332

DATE MAILED: 02/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev. 2/95)
*U.S. GPO: 2000-473-000/44602

Office Action Summary	Application No. 09/427,699	Applicant(s) ZHAO ET AL.	
	Examiner Shin-Lin Chen	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2000*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
18)☐ Interview Summary (PTO-413) Paper No(s). _____
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other.

DETAILED ACTION

It should be noted that the examiner for this patent application has been changed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

The amendment filed 12-6-00 has been entered. Claim 6 has been canceled. Claims 1 and 8 have been amended. Claims 1-5 and 7-12 are pending.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-5 and 7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8, 10, 13, 14 and 19 of U.S. Patent No. 5,753,263. Although the conflicting claims are not identical, they are not patentably distinct

from each other because of the reasons set forth in the preceding Official action mailed 6-6-00 (Paper No. 5) and the reason that it would have been obvious for one of ordinary skill in the art to place a nucleotide sequence operably linked to a control sequence as claimed in claim 2 of the present application in an expression system in order to effect the expression of said nucleotide sequence.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "pEDFP-p21" in claim 10 is vague and renders the claim indefinite. It is unclear what the term "pEDFP-p21" means. The specification fails to define the term "pEDFP-p21".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

6. Claims 1-5 and 7 remain rejected under 35 U.S.C. 102(e) as being clearly anticipated by Lishko et al., US Patent No. 5,753,263.

Applicants request that the present rejection be held in abeyance until the indication of allowance subject matter, upon which indication, inventorship will be investigated. Claims 1-5 and 7 remain rejected under 35 U.S.C. 102(e) for the reasons set forth in the preceding Official action mailed 6-6-00 (Paper No. 5).

Claims 1-5 and 7 remain rejected under 102(f) or (g) as the issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of the present invention needs to be resolved.

Applicants argue that the scope of the claims in the present application are different from the scope in the '263 patent and "Examiner has not made a rejection under either of these two subsections of 102". This is not found persuasive because claims 1-5 and 7 are rendered obvious to claims 1-3, 8, 10, 13, 14 and 19 of U.S. Patent No. 5,753,263 and although the conflicting claims are not identical, they are not patentably distinct from each other. The scope of the claims in the present application is encompassed by the scope in the '263 patent. Further, the middle

section of page 12 and second half of page 13 of the Official action mailed 6-6-00 (Paper No. 5) did indicate the rejection of claims 1-5 and 7 under 102(f) or (g). Thus, the assignee is required to state which entity is the prior inventor of the conflicting subject matter.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lishko et al., US Patent No. 5,753,263 in view of Ludin et al., 1996 (Gene, Vol. 173, p. 107-111).

Claims 8-12 are directed to a method to observe the *in vitro* expression of p21 in hair follicle cells on a histoculture via an expression system, such as a plasmid, a retroviral vector or an adenoviral vector, and the histoculture produced, wherein the nucleotide sequence encoding p21 protein is fused to a nucleotide sequence encoding a fluorescence protein.

Lishko teaches generation of a histoculture of skin and liposome-mediated delivery of beneficial agents to hair follicle by using said histoculture-containing skin sample and fluorescent dye calcein to allow detail observation of the hair follicle cells during the treatment with therapeutic liposomes (e.g. column 34). Lishko also teaches an expression system expressing a cell cycle inhibitor, such as p21, could be used for the method to introduce a composition that inhibits the loss of hair caused by chemotherapeutic agent selectively to the hair follicles of a subject (e.g. column 46). Lishko does not teach using fluorescent protein.

Ludin teaches construction of pBact-NGFP and pBact-CGFP that incorporate GFP as a fluorescent tag at N- or C- terminus of the produced protein and produces GFP-tagged microtubule-associated protein (MAP), MAP2c and Tau34. Ludin also teaches that "the pBact-NGFP and pBact-CGFP expression vectors represent a fast and convenient way to produce fluorescently tagged polypeptides of selected sequences encoding whole proteins or fragments for the analysis of function and dynamic events in living cells "(e.g. summary).

It would have been obvious for one of ordinary skill at the time of the invention to substitute the fluorescent dye as taught by Lishko with a nucleotide sequence encoding the green fluorescent protein (GFP) as taught by Ludin and fuse said nucleotide sequence to a nucleotide

sequence encoding p21 to observe the *in vitro* expression of p21 in follicle cells on a histoculture and for the method of introducing a composition that inhibits the loss of hair caused by chemotherapeutic agent selectively to the hair follicles of a subject as taught by Lishko.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Kimberly Davis, whose telephone number is (703) 305-3015.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

DEBORAH J. R. CLARK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Shin-Lin Chen, Ph.D.